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10/541,621	07/06/2005	James C Jensen	Nutri-Check-USNP	8393
33549 7590 09/30/2008 SANTANGELO LAW OFFICES, P.C. 125 SOUTH HOWES, THIRD FLOOR FORT COLLINS, CO 80521			EXAMINER FISHER, ABIGAIL L	
			ART UNIT	PAPER NUMBER
			1616	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

BarbH@idea-asset.com
CherylS@idea-asset.com
SantangeloLawOfficesPTOnotices@yahoo.com

Office Action Summary	Application No. 10/541,621	Applicant(s) JENSEN ET AL.	
	Examiner ABIGAIL FISHER	Art Unit 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 10-20,43-46,54-69,73-82,105,106,110-113 and 132-136 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 10-20,43-46,54-69,73-82,105,106,110-113 and 132-136 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>7/6/05</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claims 10-20, 43-46, 54-69, 73-82, 105-106, 110-113 and 132-136 are pending.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on July 6 2005 was considered by the examiner.

Claim Objections

Claims 10 and 18 are objected to because of the following informalities: the claims as written states "useful to use of". The English of these claims are incorrect. The examiner believes the sentence should be "useful to use with". If the applicants disagree with the examiner's interpretation, the examiner suggests amending the claim to place it in better English format. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 12, 18, 46, 60, 63, 106, 110, 111 and 132-136 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 12 as currently written is vague and indefinite. It is unclear what the term “demonstratively minimizing the likelihood” means. The resulting claim has no clear scope as this phrase is not clearly defined in the specification and subsequently, the resulting claim does not clearly set forth the metes and bounds of the patent protection desired.

The term "arguably relevant" in claim 18 is a relative term which renders the claim indefinite. The term "arguably relevant" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Claim 18 as currently written is vague and indefinite. The claims contain the phrase “user-practical procedure”. The claim does not define what the user-practical procedure is nor does the specification provide a clear definition of what constitutes a user-practical procedure. Consequently, the resulting claim does not clearly set forth the metes and bounds of the patent protection desired.

Claim 43 is vague and indefinite. Claim 43 recites a selected amount of said supplement. The resulting claim is indefinite because it is unclear what constitutes a "selected amount". The instant specification provides no guidance as to what amounts would be considered a “selected amount”. Consequently, the resulting claim does not clearly set forth the metes and bounds of the patent protection desired.

Claim 46 as currently written is vague and indefinite. The claims contain the phrase “user-practical test”. The claim does not define what the user-practical test is

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nor does the specification provide a clear definition of what constitutes a user-practical test. Consequently, the resulting claim does not clearly set forth the metes and bounds of the patent protection desired.

Claim 60 as currently written is vague and indefinite. The claim contains the term "empowering". Neither the claim nor the specification gives a clear definition of what "empowering a test recording option" means or how this step is performed. Consequently, the resulting claim does not clearly set forth the metes and bounds of the patent protection desired.

Claim 63 as currently written is vague and indefinite. The claim contains the term "enticing". Neither the claim nor the specification gives a clear definition of what "enticing use of said inter-net based recording system" means or how this step is performed. Consequently, the resulting claim does not clearly set forth the metes and bounds of the patent protection desired.

The term "directly relevant" in claim 106 is a relative term which renders the claim indefinite. The term "directly relevant" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

The term "indirectly relevant" in claim 110 is a relative term which renders the claim indefinite. The term "indirectly relevant" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one

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of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Claim 111 as currently written is vague and indefinite. The claim contains the term "publicly espoused test modality". Neither the claim nor the specification gives a clear definition of what "publicly espoused test modality" means or how one determines if a test is publicly espoused. Consequently, the resulting claim does not clearly set forth the metes and bounds of the patent protection desired.

Claim 112 as currently written is vague and indefinite. The claim contains the term "popularly used test". Neither the claim nor the specification gives a clear definition of what "popularly used test" means or how one determines if a test is popularly used. Consequently, the resulting claim does not clearly set forth the metes and bounds of the patent protection desired.

Claim 113 as currently written is vague and indefinite. The claim contains the term "personal baseline test". Neither the claim nor the specification gives a clear definition of what "personal baseline test" means or how one determines if a test is a personal baseline test. Consequently, the resulting claim does not clearly set forth the metes and bounds of the patent protection desired.

Claims 69, 78, 80-81, 105, 132, 134 and 136 as currently written are vague and indefinite. The claims recite the phrase "selected from the group comprising" or "from a group comprising". **Note MPEP 2173.05(h)** "Alternative expressions are permitted if they present no uncertainty or ambiguity with respect to the question of scope or clarity of the claims...It is improper to use the term comprising instead of consisting of". *Ex*

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parte Dotter, 12 USPQ 382 (Bd. App. 1931). The resulting claims are indefinite because the use of the term comprising results in the scope of the claims to be uncertain. It is unclear if the group comprises only these components included after comprising or other components would be acceptable.

Claims 132-136 are directed to a system as described in claim 18. However, claim 18 is directed a method of making a supplement available not a system. Therefore it is unclear what system is being claimed.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Applicant Claims
2. Determining the scope and contents of the prior art.
3. Ascertaining the differences between the prior art and the claims at issue, and resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of

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the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 10, 14-15, 18-20, 43-46, 54-61, 66, 69, 73-81, 105-106, 110-113, 132-136 are rejected under 35 U.S.C. 103(a) as being unpatentable over Azar et al. (US PG PUB No. 2001/0012636) in view of Cherukuri et al. (US Patent No. 4971787).

Applicant Claims

Applicant claims a method of providing a supplement comprising the steps of : contain an amount of calcium supplement in a distribution container; selecting a plurality of saliva pH test trips; establishing a saliva pH test strip procedures: compactly assembling said plurality of saliva pH test strips; attaching said compactly assembled plurality of saliva pH test strips to said distribution container; externally displaying the presence of said plurality of saliva pH test strips to potential purchasers of said calcium supplement; providing said amount of said calcium supplement to a purchaser; and providing said compactly assembled plurality of saliva pH test strips to said purchaser of said calcium supplement at about the time of accomplishing said step of providing said amount of said calcium supplement to a purchaser.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

Azar et al. is directed to chewing gum with pH indicator. A kit is provided that contains a chewing gum and one or more pH sensitive members including at least one pH sensitive substance (abstract). Figure 8 is directed to the container for the kit. It comprises one housing member for the pH sensitive members (i.e. pH test strips) and another housing member for the gum. It is taught that the pH sensitive members are for checking the pH level of oral fluids (paragraph 0071). It is taught that provided the pH does not drop below 5.3, the dental enamel remains intact but below this level crystals of apatite dissolve. If the pH returns fairly rapidly above 5.3, the ions will go back into the enamel and recrystallize. This recrystallization takes longer in an acid environment (paragraph 0003). It is taught that the kit allows for checking the pH levels in one's saliva and oral fluids (paragraph 007). It is taught that the consumer chewing the gum would use the gum for raising the pH level in the mouth after a meal, a snack, sugar drink, or consuming food or drink leading to oral acidification. The indicator provides an estimation of the approximate time for which the chewing gum needs to be continued in order to reach the desired pH level (paragraph 0080). It is taught that the user may elect to perform the pH checks at any time before, during and after the chewing of the gum (paragraph 0171). Figure 5G is directed to diagram illustrating a reference color scale. This reference color scale provides a way for the user to compare the color of the scale to those on the indicator to determine the respective pH of the saliva (paragraph 0142). It is taught that the pH sensitive substrate undergoes a visibly detectable color change when exposed to saliva or oral fluids (paragraph 0118).

**Ascertainment of the Difference Between Scope the Prior Art and the Claims
(MPEP §2141.012)**

Azar et al. do not teach that the gum comprises calcium. However, this deficiency is cured by Cherukuri et al.

Cherukuri et al. is directed to an antacid chewing gum. The invention is directed to a chewing gum useful for delivery of measured doses of antacids (column 1, lines 16-18). Examples of antacids include calcium in the form of insoluble calcium salts which allows for a delivery system for supplemental calcium. It is taught that the need for supplemental calcium has recently been discovered in mature and older women particularly after they reach menopause. Additionally calcium used to treat osteoporosis (column 8, lines 4-12).

***Finding of Prima Facie Obviousness Rational and Motivation
(MPEP §2142-2143)***

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to combine the teachings of Azar et al. and Cherukuri et al. and incorporated calcium into the chewing gum of Azar et al. One of ordinary skill in the art would have been motivated to incorporate calcium for the added benefit of an antacid as well as a delivery system for supplemental calcium as taught by Cherukuri et al.

Regarding instant claims 14-15, Figure 8 of Azar et al. is more of a rectangular shaped container. The limitation of a bottle and cap is merely a design feature and imparts no critically to the actual composition. **Note MPEP 2144.04:** "if the feature is ornamentation only or does not have a mechanical function then it can not be patentably distinguished from the prior art.

Regarding the limitation that the test modality is compactly assembled to the distribution container, figure 8 clearly shows that the housing member for the test strips is attached directed to the housing member for the supplements.

Regarding the limitation of an information display, it would have been obvious to one of ordinary skill in the art to combine the teachings of Azar et al. and Cherukuri et al. and utilize a kit for the supplement and test strips. One of ordinary skill in the art would have been motivated to utilize a kit in order to package and ship the formulation as well as to provide instructions for a consumer/provider on how to utilize the product. "Where the printed matter is not functionally related to the substrate, the printed matter will not distinguish the invention from the prior art in terms of patentability." *In re Ngai*, 367 F.3d 1336, 70 USPQ2d 1862 (Fed. Cir. 2004). **See MPEP 2112.01 [R-3]**. The applicant has not indicated that the instructions indicate some unobvious functional relationship between the product and the instructions.

Regarding the no-cost increment limitation, since Azar et al. teach the strips and gum in the same container, there is a reasonable expectation that when sold the whole device would be priced at one amount and the inclusion of the strips would not cost the consumer more.

Regarding the claimed time frame of test yields, Azar et al. teach the pH indicator changes color upon contact with the saliva or oral fluids. Azar et al. do not state how long it takes for this to occur. A reasonable interpretation would be that it happens rather quickly. Applicants have claimed that the test results can occur within 300 seconds, which is a time frame that can reasonably be interpreted from the teachings of

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Azar et al. Additionally, based on applicants description of the pH test strips as compared to those of Azar et al., it would appear that the test strips would yield results in similar if not the same time frame as instantly claimed.

Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the instantly claimed invention. Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Claims 11-12, 16-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Azar et al. in view of Cherukuri et al. and in further view of Potter (US Patent No. 3217874) and Vette (US Patent No. 6302301).

Applicant Claims

Applicant claims that the container is sealed and utilized a tamper-proof seal.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

The teachings of Azar et al. and Cherukuri et al. are set forth above. Specifically, Azar et al. is directed to a kit comprising saliva pH test strips and chewing gum. Cherukuri et al. is directed to chewing gum comprising supplemental calcium.

Ascertainment of the Difference Between Scope the Prior Art and the Claims (MPEP §2141.012)

Azar et al. and Cherukuri et al. do not claim that the container is sealed or contains a tamper-proof seal. However, these deficiencies are cured by Potter and Vette.

Potter is directed to packaging for a plurality of containers. It is taught that when packaging two or more containers utilizing a thermoplastic film and shrinking and closely fitting said film around the containers provides a stronger, more durable and attractive packages as compared to the prior art (column 1, lines 9-15 and 67-71, column 2, lines 1-2). The shrink wrapping allows for the contents of the containers to be visible through the package (column 1, lines, 58-59).

Vette is directed to dispensing container with a sliding vale and tamper-proof device. Figure 3 is directed to a device with a similar shape to that of Azar et al. It is taught that these devices prevent unwanted opening of a package container and in the case of unauthorized opening allows the user to see that it has been opened (column 1, lines 7-10). The device comprises a sealing strip and a cover (column 8, lines 14-21).

***Finding of Prima Facie Obviousness Rational and Motivation
(MPEP §2142-2143)***

It would have been obvious to one of ordinary skill in the art to combine the teachings of Azar et al., Cherukuri et al., Potter and Vette and utilize shrink wrapping around the container. One of ordinary skill in the art would have been motivated to utilize shrink wrapping to provide a stronger, more durable and attractive package as taught by Potter.

It would have been obvious to one of ordinary skill in the art to combine the teachings of Azar et al., Cherukuri et al., Potter and Vette and utilize a tamper-proof

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device. One of ordinary skill in the art would have been motivated to utilize the tamper proof device of Vette for the container of Azar et al. Both devices are directed to similar shaped devices and Vette teach that their device provides unwanted opening of a package container and allows for notification of unauthorized opening.

Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the instantly claimed invention. Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Azar et al. in view of Cherukuri et al. and in further view of Assoumani (Agro Food Industry Hi-Tech, 1998).

Applicant Claims

Applicant claims a coral calcium supplement.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

The teachings of Azar et al. and Cherukuri et al. are set forth above. Specifically, Azar et al. is directed to a kit comprising saliva pH test strips and chewing gum. Cherukuri et al. is directed to chewing gum comprising supplemental calcium.

Ascertainment of the Difference Between Scope the Prior Art and the Claims (MPEP §2141.012)

Azar et al. and Cherukuri et al. do not specify that the calcium is coral calcium. However, this deficiency is cured by Assoumani.

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Assoumani is directed to the physical-chemical properties of calcium sources. It is taught that aquamin, which is a seaweed derived calcium, provides the best buffering capacity (figure 2) and is an excellent antacid product (page 34, third column, second paragraph).

***Finding of Prima Facie Obviousness Rational and Motivation
(MPEP §2142-2143)***

It would have been obvious to one of ordinary skill in the art to combine the teachings of Azar et al., Cherukuri et al., and Assoumani and utilize aquamin as the calcium source. One of ordinary skill in the art would have been motivated to utilize aquamin as it is taught as providing the best buffering capacity out of other calcium sources tested and is an excellent antacid product as taught by Assoumani.

Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the instantly claimed invention. Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Claims 62-65, 82 are rejected under 35 U.S.C. 103(a) as being unpatentable over Azar et al. in view of Cherukuri et al. and in further view of Brown et al. (US Patent No. 5879163).

Applicant Claims

Applicant claims an internet-based recording system.

**Determination of the Scope and Content of the Prior Art
(MPEP §2141.01)**

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The teachings of Azar et al. and Cherukuri et al. are set forth above. Specifically, Azar et al. is directed to a kit comprising saliva pH test strips and chewing gum.

Cherukuri et al. is directed to chewing gum comprising supplemental calcium.

**Ascertainment of the Difference Between Scope the Prior Art and the Claims
(MPEP §2141.012)**

Azar et al. and Cherukuri et al. do not claim an internet-based recording system. However, this deficiency is cured by Brown et al.

Brown et al. is directed to an automated system which include a questionnaire generator for questioning the individual to determine their motivational drivers and comprehension capacity, a profile generator, a translator which receives clinical data relating to a current health condition of the individual and translate that clinical data into a profile code. An evaluation program which evaluates education responses and provides profile updates for targeting subsequent educational material (abstract). The automated system is connected to the remote terminal via a communication network (column 4, lines 58-59). The communication network is a public network such as the internet (column 6, lines 49-51). The translator receives updated clinical data to determine if an individual has made an improvement and generates a new profile code for targeting education material to the individual (column 11, lines 49-44). The invention is to provide an automated system and method for customized health education (column 4, lines 36-39).

**Finding of Prima Facie Obviousness Rational and Motivation
(MPEP §2142-2143)**

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It would have been obvious to one of ordinary skill in the art to combine the teachings of Azar et al. Cherukuri et al. and Brown et al. and utilize the automated system of Brown et al. for monitoring the progress of an individual. One of ordinary skill in the art would have been motivated to utilize the system of Brown et al. as it provides a means to evaluate and educate the consumer on health related issues. It provides a way to track and monitor an individual's progress and provide updated profiles with new information so the individual can reach specific goals. It also provides motivational drivers for individuals to help them meet their health related goals thereby allowing greater consumer compliance.

Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the instantly claimed invention. Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ABIGAIL FISHER whose telephone number is (571)270-3502. The examiner can normally be reached on M-Th 9am-6pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Abigail Fisher
Examiner
Art Unit 1616

AF

/Mina Haghighatian/
Primary Examiner, Art Unit 1616